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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,746	05/12/2005	Julia Eva Diederichs	05-066	8998

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,746	DIEDERICHS, JULIA EVA	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-30* is/are pending in the application.

4a) Of the above claim(s) *13-27,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 10/24/2009 is acknowledged.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for moisturizing or calming skin or mucous membrane by applying a substance containing the phospholipid gel to the skin or mucous membrane, does not reasonably provide enablement for moisturizing or calming skin or mucous membrane by generally applying the substance (to any substrate in any manner). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to moisturize or calm skin or mucous membranes by generally applying a substance containing the phospholipid gel (to any substrate by any means), commensurate in scope with the claim.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has

stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention and relative skill level

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The invention relates to moisturizing or calming skin or mucous membranes. The relative skill of those in the art is high, that of an MD or PhD.

2. The breadth of the claims

The claims encompass "applying a substance containing the phospholipid gel according to claim 13". This recitation of "applying" is interpreted as a general applying which encompasses application to any substrate (i.e. to a person, to an object) in any manner (i.e. to a person, administering the substance topically, orally, intravenously, etc; to an object, combining the substance with the object by any means). By carrying out this method, normal or diseased skin or mucous membranes are moisturized or calm. For illustrative purposes only, as the method step is only to a general applying, the claims encompass applying the phospholipid substance to the roof of a house, which results in skin or mucous membrane of a person being moisturized or calmed.

3. Unpredictability of the art, the amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for generally applying this substance (to any substrate in any manner) and thereby moisturizing or calming someone's skin or mucous membrane. No reasonably specific guidance is provided concerning useful therapeutic protocols for generally applying the substance and thereby moisturizing or calming skin or mucous membranes, other than topically administering the phospholipid gel substance to a patient. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed method step could be carried out to moisturize or calm normal or diseased skin or mucous membranes over the scope of the claim. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

5. Suggested alternative language

The Examiner suggests replacing “the method comprising the step applying a substance containing the phospholipid gel according to claim 13" with "the method comprising the step of topically administering a substance containing the phospholipid gel according to claim 13 to the skin or mucous membrane". The latter method step is enabled by the specification. To be clear, this claim language would overcome the current enablement rejection under 35 U.S.C. 112, first paragraph. It would not, however, overcome the other rejections currently made against the invention.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what constitutes “calming”

and what constitutes “normal skin”. These terms are not defined by the specification.

"Calming skin” is not a term of art. Is “calming” skin reducing irritation of the skin? Inflammation of the skin? Is “calming” skin treating any conditions which irritates/reddens the skin: acne, boils, cellulitis, hives, psoriasis, warts, allergic reactions, measles, chickenpox, shingles, etc? For these reasons, it is unclear what diseases or conditions are treated by “calming” skin.

"Normal skin” is not a term of art. On the one hand, “normal skin” may be given a meaning of skin that is not diseased. This is consistent with the recitation of “normal or diseased skin” in claim 28, where “normal” and “diseased” are alternatives. However, this meaning is inconsistent with the recitation of “calming”, as it is unclear how “normal skin” could be calmed. If “normal skin” is skin that is not diseased, then how could it be calmed, i.e. be treated for irritation, inflammation, acne, boils, cellulitis, hives, psoriasis, warts, allergic reactions, measles, chickenpox, shingles, etc? Is not the presence of these diseases an indication that the skin is diseased, and not normal. For these reasons, it is unclear what types of skin are encompassed by “normal skin”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5741513 ('513; document already in record). '513 discloses a method of reducing inflammation in diseased skin (i.e. calming diseased skin) by topically administering (i.e. applying) a substance comprising phosphatidylcholine (a neutral phospholipid) and an acidic phospholipid, such as phophatidic acid or phosphatidylinositol (both negatively charged phospholipids) (see col 3, lines 24-46; col 4, lines 14-28; col 5, lines 5-40). Phosphatidylcholine is a zwitterion, it

comprises both a positive and negative charge, and is overall neutral. This is a "neutral phospholipid" within the meaning of the instant specification (see page 2, line 21 to page 3, line 7).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 25, 2010